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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/552,287

01/04/2007

Anthony Futerman

30227

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67801

7590

07/24/2009

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EXAMINER

STEADMAN, DAVID J

ART UNIT

PAPER NUMBER

1656

MAIL DATE

DELIVERY MODE

07/24/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<p align="center">Advisory Action Before the Filing of an Appeal Brief</p>	<p>Application No. 10/552,287</p>	<p>Applicant(s) FUTERMAN ET AL.</p>	
	<p>Examiner David J. Steadman</p>	<p>Art Unit 1656</p>	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 08 July 2009 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
(a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);
(b) ☐ They raise the issue of new matter (see NOTE below);
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
(d) ☒ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
The status of the claim(s) is (or will be) as follows:
Claim(s) allowed: _____.
Claim(s) objected to: _____.
Claim(s) rejected: 123,124,129 and 133-138.
Claim(s) withdrawn from consideration: 139-156.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:
See Continuation Sheet.
12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____.
13. ☐ Other: _____.

/David J. Steadman/
Primary Examiner, Art Unit 1656

Continuation of 3. NOTE: Applicant's amendment after final rejection, filed on 7/8/09, is acknowledged. While the claim amendment would appear to obviate the outstanding rejections under 35 U.S.C. 112, first paragraph, the amendment has not been entered because entry of the amendment would necessitate at least further consideration for reasons set forth below. See MPEP § 714.13.

Continuation of 11. does NOT place the application in condition for allowance because: The request for reconsideration in the reply filed on 7/8/09 has been fully considered, however, the amendment does not place the application in condition for allowance. The amendment to the claims filed on 7/8/09 has not been entered because the claims as amended would necessitate consideration of a new rejection under 35 U.S.C. 112, second paragraph for reasons that follow. The instant amendment to claim 129 part (iii) requires glycosylation residues Asn59, Asn146, and Asn270 to be unglycosylated. However, claim 134 requires "at least one glycosylation residue...has at least one exposed mannose residue", which would appear to require at least one glycosylation residue of Asn59, Asn146, and/or Asn270 to have a mannose moiety, i.e., to be "re-glycosylated". As such, the scope of claim 134 is unclear.

The claims as amended would further necessitate consideration of a new rejection under 35 U.S.C. 112, first paragraph, written description for reasons that follow. The instant amendment to claims 123 and 129 recite preparation of the glucocerebrosidase molecule by dialysis of any glucocerebrosidase, which results in glycosylation of Asn19 and deglycosylation of Asn59, Asn146, and Asn270. However, the specification discloses only a single representative species of glucocerebrosidase polypeptides that, when treated according to the method as recited in the claims, result in SEQ ID NO:1 with glycosylation of Asn19 and deglycosylation of Asn59, Asn146, and Asn270, i.e., CEREZYME (p. 80, top).

Applicant's remarks in the amendment filed on 6/9/09 have been fully considered. However, in view of the non-entry of the amendment, applicant's arguments are not found persuasive to overcome the outstanding rejection(s) as set forth in the final Office action mailed on 4/8/09 for the reasons of record stated therein.

Even if the after final amendment were entered, the rejections under 35 U.S.C. 102/103 and 103 would be maintained for reasons that follow. While the Declaration under 37 CFR 1.132, filed on 7/8/09, states that co-author Andrew A. McCarthy of the reference of Dvir was not a co-inventor, the reference of Dvir is still "by others" because the inventive entity includes inventor Svetlana Adamsky, which name is not listed in the authorship of the Dvir reference. In other words, the entity of authors as listed in the Dvir reference, excluding McCarthy, is different from the inventive entity and thus is "by others". See MPEP 2132.III, which states, "The term 'others' in 35 U.S.C. 102(a) refers to any entity which is different from the inventive entity. The entity need only differ by one person to be 'by others.'"